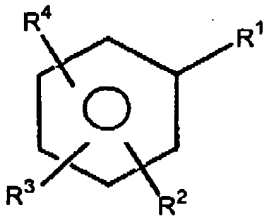
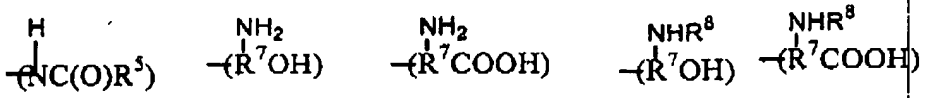
KCC 4749.2
K-C 16,858.2
PATENT

Listing of Claims:

1. (Original) An exoprotein inhibitor for inhibiting the production of exoproteins from Gram positive bacteria in and around the vagina comprising a non-absorbent substrate for insertion into a vagina being selected from the group consisting of a non-absorbent incontinence device, a barrier birth control device, a tampon applicator, and a douche, the non-absorbent substrate having deposited thereon an effective amount of a first active ingredient having the general formula:



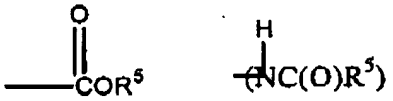

wherein $R^1$ is selected from the group consisting of H, $-\overset{O}{\overset{\|}{C}}OR^5$ $-OR^5$, $-R^6C(O)H$, $-R^6COOH$, $-OR^6COOH$, $-C(O)NH_2$,




and $NH_2$ and salts thereof; $R^5$ is a monovalent saturated or unsaturated aliphatic hydrocarbyl moiety; $R^6$ is a divalent saturated or unsaturated aliphatic hydrocarbyl moiety; $R^7$ is a

trivalent saturated or unsaturated aliphatic hydrocarbyl moiety; $R^8$ is a monovalent substituted or unsubstituted saturated or unsaturated aliphatic hydrocarbyl moiety which may or may not be interrupted with hetero atoms; $R^2$, $R^3$, and $R^4$ are independently selected from the group consisting of H, OH, COOH, and $-C(O)R^9$; $R^9$ is hydrogen or a monovalent saturated or unsaturated aliphatic hydrocarbyl moiety, wherein the first active ingredient is effective in inhibiting the production of exoprotein from Gram positive bacteria.

2. (Withdrawn) The exoprotein inhibitor as set forth in claim 1 wherein $R^1$ is selected from the group consisting of



$-OR^5$, and salts thereof and wherein $R^5$ is a monovalent saturated aliphatic hydrocarbyl moiety having from 1 to about 15 carbon atoms.

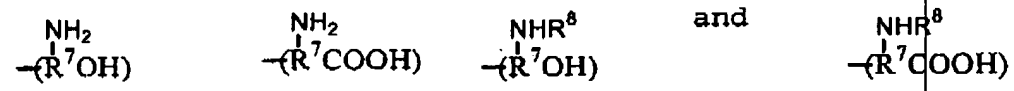
3. (Withdrawn) The exoprotein inhibitor as set forth in claim 2 wherein $R^5$ is a monovalent saturated aliphatic hydrocarbyl moiety having from 1 to about 10 carbon atoms.

4. (Withdrawn) The exoprotein inhibitor as set forth in claim 1 wherein $R^1$ is selected from the group consisting of $-R^6C(O)H$, $-R^6COOH$, and $-OR^6COOH$ and wherein $R^6$ is a divalent saturated or unsaturated aliphatic hydrocarbyl moiety having from 1 to about 15 carbon atoms.

5. (Withdrawn) The exoprotein inhibitor as set forth in claim 4 wherein $R^6$ is a divalent saturated or unsaturated aliphatic hydrocarbyl moiety having from 1 to about 10 carbon atoms.

6. (Withdrawn) The exoprotein inhibitor as set forth in claim 4 wherein $R^6$ is a divalent saturated or unsaturated aliphatic hydrocarbyl moiety having from 1 to about 6 carbon atoms.

7. (Withdrawn) The exoprotein inhibitor as set forth in claim 1 wherein $R^1$ is selected from the group consisting of



and wherein $R^7$ is a trivalent saturated or unsaturated aliphatic hydrocarbyl moiety having from 1 to about 15 carbon atoms.

8. (Withdrawn) The exoprotein inhibitor as set forth in claim 7 wherein $R^7$ is a trivalent saturated or unsaturated aliphatic hydrocarbyl moiety having from 1 to about 10 carbon atoms.

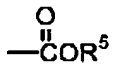
9. (Withdrawn) The exoprotein inhibitor as set forth in claim 7 wherein $R^7$ is a trivalent saturated or unsaturated aliphatic hydrocarbyl moiety having from 1 to about 4 carbon atoms.

10. (Withdrawn) The exoprotein inhibitor as set forth in claim 1 wherein $R^1$ is $-R^6COOH$, $R^6$ is a divalent unsaturated

aliphatic hydrocarbyl moiety having from 1 to about 6 carbon atoms, and $R^2$, $R^3$, and $R^4$ are hydrogen.

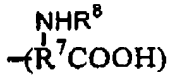
11. (Original) The exoprotein inhibitor as set forth in claim 1 wherein $R^1$ is $-C(O)NH_2$, $R^2$ is OH, and $R^3$ and $R^4$ are hydrogen.

12. (Withdrawn) The exoprotein inhibitor as set forth in claim 1 wherein $R^1$ is



and $R^5$ is a monovalent saturated aliphatic hydrocarbyl group having from 1 to about 4 carbon atoms.

13. (Withdrawn) The exoprotein inhibitor as set forth in claim 1 wherein $R^1$ is



and $R^7$ is a trivalent saturated aliphatic hydrocarbyl moiety having from 1 to about 4 carbon atoms and $R^8$ is $C(O)CH_3$.

14. (Original) The exoprotein inhibitor as set forth in claim 1 wherein $R^2$ is OH and $R^3$ is COOH.

15. (Original) The exoprotein inhibitor as set forth in claim 1 wherein the first active ingredient is selected from the group consisting of trans-cinnamic acid, 4-hydroxybenzoic acid,

methyl ester, 2-hydroxybenzoic acid, 2-hydroxybenzamide, acetyl tyrosine, 3, 4, 5-trihydroxybenzoic acid, lauryl 3, 4, 5-trihydroxybenzoate, 4-hydroxy-3-methoxybenzoic acid, para-aminobenzoic acid, and acetaminophen.

16. (Original) The exoprotein inhibitor as set forth in claim 1 wherein the first active ingredient is present in an amount of at least about 0.01 micromoles per gram of non-absorbent substrate.

17. (Original) The exoprotein inhibitor as set forth in claim 1 wherein the first active ingredient is present in an amount from about 0.5 micromoles per gram of non-absorbent substrate to about 100 micromoles per gram of non-absorbent substrate.

18. (Original) The exoprotein inhibitor as set forth in claim 1 wherein the first active ingredient is present in an amount from about 1.0 micromoles per gram of non-absorbent substrate to about 50 micromoles per gram of non-absorbent substrate.

19. (Original) The exoprotein inhibitor as set forth in claim 1 further comprising a pharmaceutically active material selected from the group consisting of antimicrobials, antioxidants, anti-parasitic agents, antipruritics, astringents, local anaesthetics and anti-inflammatory agents.

20. (Original) The exoprotein inhibitor as set forth in claim 1 further comprising an effective amount of a second active ingredient, said second active ingredient comprising a

compound with an ether, ester, amide, glycosidic, or amine bond linking a $C_8$-$C_{18}$ fatty acid to an aliphatic alcohol wherein the second active ingredient is effective in substantially inhibiting the production of exoprotein from Gram positive bacteria.

21. (Withdrawn) The exoprotein inhibitor as set forth in claim 20 wherein the $C_8$-$C_{18}$ fatty acid is linked to a polyalkoxylated sulfate salt.

22. (Original) The exoprotein inhibitor as set forth in claim 1 further comprising an effective amount of a second active ingredient having the general formula:

$$R^{10}——O——R^{11}$$

wherein $R^{10}$ is a straight or branched alkyl or straight or branched alkenyl having from 8 to about 18 carbon atoms and $R^{11}$ is selected from the group consisting of an alcohol, a polyalkoxylated sulfate salt and a polyalkoxylated sulfosuccinate salt wherein the second active ingredient is effective in substantially inhibiting the production of exoprotein from Gram positive bacteria.

23. (Original) The exoprotein inhibitor as set forth in claim 22 wherein $R^{10}$ is a straight or branched alkyl group.

24. (Original) The exoprotein inhibitor as set forth in claim 22 wherein $R^{10}$ is a straight or branched alkenyl group.

25. (Original) The exoprotein inhibitor as set forth in claim 22 wherein $R^{10}$ is obtained from the group consisting of

caprylic acid, capric acid, lauric acid, myristic acid, palmitic acid and stearic acid.

26. (Original) The exoprotein inhibitor as set forth in claim 22 wherein $R^{11}$ is an aliphatic alcohol.

27. (Original) The exoprotein inhibitor as set forth in claim 26 wherein $R^{11}$ is an aliphatic alcohol selected from the group consisting of glycerol, glycol, sucrose, glucose, sorbitol, and sorbitan.

28. (Original) The exoprotein inhibitor as set forth in claim 27 wherein $R^{11}$ is a glycol selected from the group consisting of ethylene glycol, propylene glycol, polypropylene glycol, and combinations thereof.

29. (Original) The exoprotein inhibitor as set forth in claim 22 wherein the second active ingredient is selected from the group consisting of laureth-3, laureth-4, laureth-5, PPG-5 lauryl ether, 1-0-dodecyl-rac-glycerol, sodium laureth sulfate, potassium laureth sulfate, disodium laureth (3) sulfosuccinate, dipotassium laureth (3) sulfosuccinate and polyethylene oxide (2) sorbitol ether.

30. (Original) The exoprotein inhibitor as set forth in claim 22 wherein the second active ingredient is present in an amount of at least about 0.0001 millimoles per gram of non-absorbent substrate.

31. (Original) The exoprotein inhibitor as set forth in claim 22 wherein the second active ingredient is present in an

amount of at least about 0.005 millimoles per gram of non-absorbent substrate.

32. (Original) The exoprotein inhibitor as set forth in claim 22 wherein the second active ingredient is present in an amount from about 0.005 millimoles per gram of non-absorbent substrate to about 0.2 millimoles per gram of non-absorbent substrate.

33. (Original) The exoprotein inhibitor as set forth in claim 22 further comprising a pharmaceutically active material selected from the group consisting of antimicrobials, antioxidants, anti-parasitic agents, antipruritics, astringents, local anaesthetics and anti-inflammatory agents.

34. (Original) The exoprotein inhibitor as set forth in claim 1 further comprising an effective amount of a second active ingredient, the second active ingredient comprising an alkyl polyglycoside effective in substantially inhibiting the production of exoprotein from Gram positive bacteria.

35. (Original) The exoprotein inhibitor as set forth in claim 34 wherein the alkyl polyglycoside has an alkyl group having from about 8 to about 18 carbon atoms.

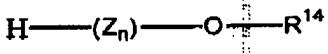
36. (Original) The exoprotein inhibitor as set forth in claim 35 wherein the alkyl group is a linear alkyl group.

37. (Original) The exoprotein inhibitor as set forth in claim 35 wherein the alkyl polyglycoside has an alkyl group having from about 8 to about 14 carbon atoms.

38. (Original) The exoprotein inhibitor as set forth in claim 34 wherein the alkyl polyglycoside has an HLB of 12 to 14.

39. (Original) The exoprotein inhibitor as set forth in claim 34 wherein the alkyl polyglycoside has an HLB of 10 to 15.

40. (Original) The exoprotein inhibitor as set forth in claim 34 wherein the alkyl polyglycoside has the general formula:



wherein Z is a saccharide residue having 5 or 6 carbon atoms, n is a whole number from 1 to 6, and $R^{14}$ is a linear alkyl group having from about 8 to about 18 carbon atoms.

41. (Original) The exoprotein inhibitor as set forth in claim 40 wherein $R^{14}$ is a linear alkyl group having from about 8 to about 14 carbon atoms.

42. (Original) The exoprotein inhibitor as set forth in claim 40 wherein $R^{14}$ is a linear alkyl group having from about 8 to about 12 carbon atoms.

43. (Original) The exoprotein inhibitor as set forth in claim 34 wherein the second active ingredient is present in an amount of at least about 0.0001 millimples per gram of non-absorbent substrate.

44. (Original) The exoprotein inhibitor as set forth in claim 34 wherein the second active ingredient is present in an

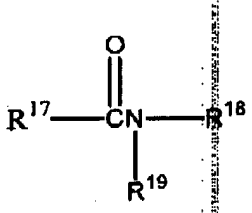
amount of at least about 0.005 millimoles per gram of non-absorbent substrate.

45. (Original) The exoprotein inhibitor as set forth in claim 34 wherein the second active ingredient is present in an amount of at least about 0.005 millimoles per gram of non-absorbent substrate to about 2 millimoles per gram of non-absorbent substrate.

46. (Original) The exoprotein inhibitor as set forth in claim 34 wherein the alkyl polyglycoside is selected from the group consisting of Glucopon 220, Glucopon 225, Glucopon 425, Glucopon 600, Glucopon 625, and TL 2141.

47. (Original) The exoprotein inhibitor as set forth in claim 1 further comprising an effective amount of a second active ingredient selected from the group consisting of glycerol monolaurate and myreth-3-myristate wherein said active ingredient is effective in substantially inhibiting the production of exoprotein from Gram positive bacteria.

48. (Original) The exoprotein inhibitor as set forth in claim 1 further comprising an effective amount of a second active ingredient having the general formula:



wherein $R^{17}$, inclusive of the carbonyl carbon, is an alkyl group having 8 to 18 carbon atoms, and $R^{18}$ and $R^{19}$ are independently selected from hydrogen or an alkyl group having from 1 to about 12 carbon atoms which may or may not be substituted with groups selected from ester groups, ether groups, amine groups, hydroxyl groups, carboxyl groups, carboxyl salts, sulfonate groups, sulfonate salts, and mixtures thereof wherein said second active ingredient is effective in substantially inhibiting the production of exoprotein from Gram positive bacteria.

49. (Original) The exoprotein inhibitor as set forth in claim 48 wherein $R^{17}$ is derived from a saturated or unsaturated fatty acid.

50. (Original) The exoprotein inhibitor as set forth in claim 49 wherein $R^{17}$ is derived from an acid selected from the group consisting of caprylic acid, capric acid, lauric acid, myristic acid, palmitic acid, and stearic acid.

51. (Original) The exoprotein inhibitor as set forth in claim 48 wherein the second active ingredient is selected from the group consisting of sodium lauryl sarcosinate, lauramide monoethanolamide, lauramide diethanolamide, lauramidopropyl dimethylamine, disodium lauramide monoethanolamide sulfosuccinate, and disodium lauroamphodiacetate.

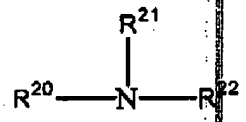
52. (Original) The exoprotein inhibitor as set forth in claim 48 wherein the second active ingredient is present in an amount of at least about 0.0001 millimoles per gram of non-absorbent substrate.

53. (Original) The exoprotein inhibitor as set forth in claim 48 wherein the second active ingredient is present in an amount of at least about 0.0005 millimoles per gram of non-absorbent substrate.

54. (Original) The exoprotein inhibitor as set forth in claim 48 wherein the second active ingredient is present in an amount from about 0.005 millimoles per gram of non-absorbent substrate to about 0.2 millimoles per gram of non-absorbent substrate.

55. (Original) The exoprotein inhibitor as set forth in claim 48 further comprising a pharmaceutically active material selected from the group consisting of antimicrobials, antioxidants, anti-parasitic agents, antipruritics, astringents, local anaesthetics and anti-inflammatory agents.

56. (Original) The exoprotein inhibitor as set forth in claim 1 further comprising an effective amount of a second active ingredient having the general formula:



wherein $R^{20}$ is an alkyl group having from about 8 to about 18 carbon atoms and $R^{21}$ and $R^{22}$ are independently selected from the group consisting of hydrogen and alkyl groups having from 1 to about 18 carbon atoms and which can have one or more substitutional moieties selected from the group consisting of

hydroxyl, carboxyl, carboxyl salts and imidazoline wherein the second active ingredient is effective in substantially inhibiting the production of exoprotein from Gram positive bacteria.

57. (Original) The exoprotein inhibitor article as set forth in claim 56 wherein $R^{22}$ comprises a carboxyl salt, the carboxyl salt having a cationic moiety selected from the group consisting of sodium, potassium and combinations thereof.

58. (Currently Amended) The exoprotein inhibitor as set forth in claim 56 wherein $R^{22}$ comprises an amine selected from the group consisting of lauramine, lauramino[[,]] propionic acid, sodium lauriminodipropionic acid, lauryl hydroxyethyl imidazoline and mixtures thereof.

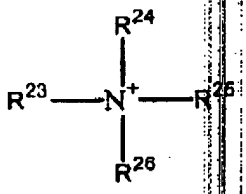
59. (Original) The exoprotein inhibitor as set forth in claim 56 wherein the second active ingredient is present in an amount of at least about 0.0001 millimoles per gram of non-absorbent substrate.

60. (Original) The exoprotein inhibitor as set forth in claim 56 wherein the second active ingredient is present in an amount of at least about 0.005 millimoles per gram of non-absorbent substrate.

61. (Original) The exoprotein inhibitor as set forth in claim 56 wherein the second active ingredient is present in an amount from about 0.005 millimoles per gram of non-absorbent substrate to about 0.2 millimoles per gram of non-absorbent substrate.

62. (Original) The exoprotein inhibitor as set forth in claim 56 further comprising a pharmaceutically active material selected from the group consisting of antimicrobials, antioxidants, anti-parasitic agents, antipruritics, astringents, local anaesthetics and anti-inflammatory agents.

63. (Original) The exoprotein inhibitor as set forth in claim 1 further comprising an effective amount of a second active ingredient having the general formula:



wherein $R^{23}$ is an alkyl group having from 8 to about 18 carbon atoms and $R^{24}$, $R^{25}$, and $R^{26}$ are independently selected from the group consisting of hydrogen and alkyl group having from 1 to about 18 carbon atoms and which can have one or more substitutional moieties selected from the group consisting of hydroxyl, carboxyl, carboxyl salts, and imidazoline wherein the second active ingredient is effective in substantially inhibiting the production of exoprotein from Gram positive bacteria.

64. (Original) The exoprotein inhibitor as set forth in claim 63 wherein the second active ingredient is triethanolamide laureth sulfate.

65. (Original) The exoprotein inhibitor as set forth in claim 63 wherein the second active ingredient is present in an

amount of at least about 0.0001 millimoles per gram of non-absorbent substrate.

66. (Original) The exoprotein inhibitor as set forth in claim 63 wherein the second active ingredient is present in an amount of at least about 0.005 millimoles per gram of non-absorbent substrate.

67. (Original) The exoprotein inhibitor as set forth in claim 63 wherein the second active ingredient is present in an amount from about 0.005 millimoles per gram of non-absorbent substrate to about 0.2 millimoles per gram of non-absorbent substrate.

68. (Original) The exoprotein inhibitor as set forth in claim 63 further comprising a pharmaceutically active material selected from the group consisting of antimicrobials, antioxidants, anti-parasitic agents, antipruritics, astringents, local anaesthetics and anti-inflammatory agents.